OCT - 1 2001

510(k) Summary
K00-3238

Submitted by:

Cares Built
75 Manchester Avenue
Keyport, NJ 07735
Phone: (800) 358-6370
Fax: (732) 739-0316

March 5, 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Contact Person:**
   Mr. Joseph Benco

2. **Device:** Clarity 7000 Solid State X-Ray Imaging Device
   Classification: 90MQB Class II
   Predicate Device: Swiss Ray Inc. Digital Add-On System K970136

3. **Intended Use:**
   Clarity 7000 is indicated for use in generating digital radiographic images of the human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

K003238
Page 2 of 2

4. **Substantial Equivalence:**

Technical Characteristics	*Clarity 7000*	Digital Add On System K970136
Field of View	43cm x 43cm	35cm x 43cm
Number of Pixels	7000 x 7000*	2100 x 2580**
Resolution	Nyquist Limit 8.13 Measured 7 lp/mm	3.0
Thickness	1.9 inches	14.2 in. (36 cm)
Gray Scale	12 Bit	12 Bit
SID Source to Image Distance	Variable	Fixed Distance 150cm
Power	140/220	3 phase 480 Vac 50/60 HZ
Compatible with existing install base	Yes	No

* Approximate net
** Based on estimated calculation

The product is similar in design and function to the Swiss Ray Inc., which was cleared by FDA under 510(k) K970136.

5. **Device Description:**
The Clarity 7000 Direct Digital Radiography Receptor is a film-less digital Receptor for Solid State X-Ray Imaging.

6. **Summary of Technological Characteristics of the Device Compared and the Substantial Equivalence:**
The Clarity 7000, a Solid State X-Ray Imaging Device, is equivalent to the Swiss Ray Inc. System K970136 with respect to the basic functionality of the System. The unit has a 17" x 17" Detector Area with 49,000,000 pixel resolution. It boasts a line pair resolution well in excess of the 3 line pairs of the Swiss Ray device and approaches 7 line pairs per millimeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Mr. Timothy Telymonde
President and CEO
Cares Built
75 Manchester Avenue
KEYPORT NJ 07735

Re: K003238
Trade/Device Name: Clarity 7000
SSXI
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic X-Ray Imaging System
Regulatory Class: II
Product Code: 90 MQB
Dated: July 25, 2001
Received: July 27, 2001

Dear Mr. Telymonde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

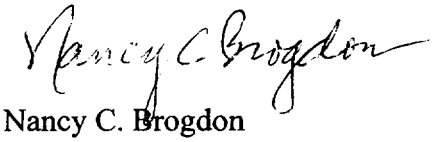
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER: K003238

DEVICE NAME: Clarity 7000

INDICATIONS FOR USE:

Clarity 7000 is indicated for use in generating digital radiographic images of the human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

This device is not intended for mammography.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K003238